



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Miao and Kay

APPLICATION No.: 09/884,901

FILED: June 18, 2001

FOR: LIVER-SPECIFIC GENE EXPRESSION
CASSETTES, AND METHODS OF USE

EXAMINER: Burkhardt

ART UNIT: 1633

CONF. No: 1704

Considered
MS

Declaration of Carol H. Miao and Mark A. Kay

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Carol H. Miao and Mark A. Kay, declare and affirm as follows:

1. We are co-inventors of the subject matter described and claimed in U.S. Patent Application No. 09/884,901, filed June 18, 2001 entitled LIVER-SPECIFIC GENE EXPRESSION CASSETTES, AND METHODS OF USE.
2. The subject matter as presently claimed relates to an expression cassette for expressing human Factor IX. The expression cassette is comprised of a hepatic locus control element, a hepatic promoter, a Factor IX coding sequence, a Factor IX Intron A, and a polyadenylation signal. In some embodiments, the cassette additionally comprises a 3' untranslated region.
3. An expression cassette previously invented by Dr. Kay is described in U.S. Patent No. 6,936,243, issued to Snyder *et al.* This previously described cassette included a promoter, a Factor IX coding sequence, and a polyadenylation signal.